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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/687,575	10/13/2000	Rima Kaddurah-Daouk	AVZ-007CP3	9336
959	7590	12/14/2004	EXAMINER	
LAHIVE & COCKFIELD, LLP. 28 STATE STREET BOSTON, MA 02109			COVINGTON, RAYMOND K	
			ART UNIT	PAPER NUMBER
			1625	

DATE MAILED: 12/14/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/687,575

Applicant(s)

KADDURAH-DAOUK ET AL.

Examiner

Raymond Covington

Art Unit

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 16 December 2003.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) See Continuation Sheet is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-4,6-8,10-18,34-39,64-74,76-84,86-96,98-106,108-118,120-128 and 130-132 is/are rejected.
- 7) ☒ Claim(s) 117 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____.
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____.

Continuation of Disposition of Claims: Claims pending in the application are 1-4,6-8,10-18,34-39,64-74,76-84,86-96,98-106,108-118,120-128 and 130-132.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

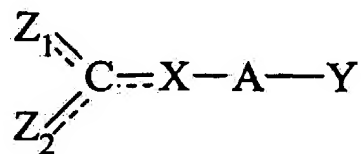
Claims 64, 66, 68, 86-90, 108-112, 130 and 132 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 64, 66, 68, 86-90, 108-112, 130 and 132 recite the limitation "mitochondrial cofactors, electron transport chain regulators" in claim 64 page 10, claim 86 page 15, claim 108 page 21, claim 130 page 29 and claim 132 page 33 of the amended claims of 9/23/04. There is insufficient antecedent basis for this limitation in the claim.

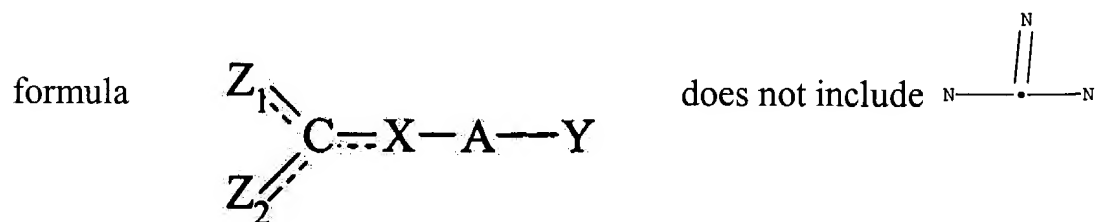
The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1-4, 6-8, 10-18, 34-39, 64-74, 76-84, 86-96, 98-106, 108-118, 120-128 and 130-132 are rejected under 35 U.S.C. 112, first paragraph, as based on a disclosure which is not enabling. The formula

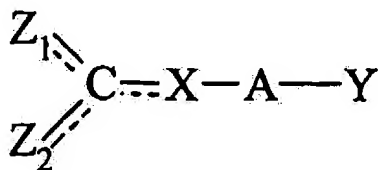


Wherein the above formula is recited as being a creatine compound in claim 1, for example, is critical or essential to the practice of the invention, but not included in the claim(s) is not enabled by the disclosure. See *In re Mayhew*, 527 F.2d 1229, 188 USPQ 356 (CCPA 1976). The definitions for the elements in



a basic component in creatine compounds even if this structure is part of a ring. It is recognized that Tables 1 and 2 on pages 26-28 of the specification are proper creatine compounds. However, the claims define creatine compounds as only those derived by the formula. Further, the specification also lacks the basic creatine structure in defining the formula. See for example page 4 of the specification.

Claims 1-4, 6-8, 10-18, 34-39, 64-74, 76-84, 86-96, 98-106, 108-118, 120-128 and 130-132 are rejected under 35 U.S.C. 112, second paragraph, as failing to set forth the subject matter which applicant(s) regard as their invention. Evidence that claims 1, 34, 64, 86, 108, 130, 132 fail to correspond in scope with that which applicant(s) regard as the invention can be found in the formula



On page 4 of applicants' specification Applicant has stated that this formula defines a creatine compound, and this statement indicates that the invention is different from what is defined in the claim(s) because creatine compounds cannot

be derived from this formula. Z_1, Z_2, X, A and Y do not contain $N \text{---} \overset{\overset{N}{||}}{\underset{\cdot}{C}} \text{---} N$ which is necessary to creatine compounds. Accordingly, it is not clear what applicants' regard as their invention.

Claims 1-4, 6-8 and 10-18 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claims contain subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention. The claims recite increasing ATP production in a subject by administering an amount effective to increase ATP production. The claims are considered as being **"reach through" claims** which contain subject matter to be discovered in the future i.e. any disorder or condition not yet correlated but may be discovered in the future to increased ATP production.

The rejection of claims 1-4, 6-8, 34-39, 75 and 84-132 under 35 USC 112 first paragraph is maintained as to claims 83, 84, 105, 106, 126 and 127 as lacking enablement for the reasons set forth in the previous office action.

The terms “human”, claims 84, 106 and 128, and “Mammal”, claims 83, 105 and 127 are not enabled. In the instant case, Applicants are claiming a method of treating humans. The nature of the pharmaceutical arts is that there is no absolute predictability even in view of the seemingly high level of skill in the art. The existence of these obstacles establishes that the contemporary knowledge in the art would prevent one of ordinary skill in the art from accepting any therapeutic regimen on its face. The instant specification does not give sufficient enabling support for use in all humans, particularly humans not in need of treatment. Reference to mammalian use is inadequate in that there is insufficient support that all mammals are subject to all of the diseases falling within the scope of the recited claims, which may be applicable to humans. In order to practice the claimed invention, one skilled in the art would have speculate which diseases could be treated or prevented using the instant claims. The number of possible diseases embraced by the claims would impose undue experimentation on the skilled art worker. Therefore, the broad terminology is not enabled because the metes and bounds cannot be ascertained.

Claim 117 is objected to under 37 CFR 1.75(c), as being of improper dependent form as depending from a canceled base claim, claim 108. Applicant is required to cancel the claim(s), or amend the claim(s) to place the claim(s) in proper dependent form, or rewrite the claim(s) in independent form.

Upon reconsideration the rejections under 35 USC 103 have been with drawn in light of applicants' amendments and comments.

No claim is allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Raymond Covington whose telephone number is (571) 272-0681. The examiner can normally be reached on M-F.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, C. Tsang can be reached on (571) 272-0562. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

/e
Raymond Covington
Examiner
Art Unit 1625

R. Desai
12/10/04